UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

COLLAZA,

Plaintiff,

-against-

JOHNSON & JOHNSON CONSUMER, INC.,

Defendant.

23-cv-06030 (ALC)

ORDER

ANDREW L. CARTER, JR., United States District Judge:

Plaintiff Evie Collaza ("Plaintiff") brings this putative class action suit against Defendant Johnson & Johnson Consumer, Inc. ("Johnson & Johnson" or "Defendant") alleging (1) violation of New York General Business Law § 349, (2) violation of New York General Business Law § 350, (3) unjust enrichment, and (4) seeking declaratory relief. ECF No. 1 ("Complaint"). Defendant moved to dismiss Plaintiff's Complaint pursuant to Fed. R. Civ. P. 12(b)(6) or, alternatively, to transfer this action to the District of New Jersey. For the reasons discussed herein, the Court finds that Plaintiff's claims are preempted by the Federal Food, Drug, & Cosmetic Act, 21 U.S.C. §§ 301 *et seq*, and, subsequently, does not consider the Parties' arguments as to transfer. Therefore, Defendant's Motion is **GRANTED**.

BACKGROUND

I. Procedural Background

Plaintiff filed the Complaint and request for issuance of summons as to Defendant Johnson & Johnson on July 13, 2023. ECF No. 1. Plaintiff's counsel then filed an affidavit of service of the Summons and Complaint on July 26, 2023. ECF No. 11. The Parties jointly moved to extend Defendant's time to file a responsive pleading by sixty days. ECF No. 12. The Court subsequently granted the request. ECF No. 14. Johnson & Johnson's counsel requested

and was granted leave to file the instant motion to dismiss. ECF Nos. 32-34. Defendant filed their motion on December 12, 2023, ECF Nos. 37, 38 ("Mot."), alongside an affidavit from defense counsel, ECF No. 39, and a Request for Judicial Notice of certain documents.[1] ECF No. 40. On January 12, 2024, Plaintiff filed their opposition to the motion to which was appended as an exhibit the Central District Court of California's decision in *Edwards v. Walmart, Inc.*, No. 18-09655-GW (N.D. Cal. Apr. 18, 2019). ECF No. 41. ("Opp."). Defendant filed their Reply on February 2, 2024. ECF No. 42 ("Reply").

II. Factual Background

All facts contained within this factual background section are taken from Plaintiff's Complaint, and, as is required at the dismissal stage, are taken as true for purposes of deciding the motion.

Defendant's Rapid Release Tylenol product fetches a higher sale price in comparison to their non-rapid release products, even those labeled as "Extra Strength," and "Regular Strength." Complaint at ¶ 31-33. Defendant also advertises that the Rapid Release Gelcaps are designed with "laser-drilled holes to release medicine quickly" and releases medicine "even faster than before." *Id.* at ¶¶ 37-38; *see also id.* at ¶¶ 42-51 (describing in detail Defendant's marketing of Rapid Release Tylenol as "fast working" and "dissolv[ing] in seconds").

Plaintiff purchased Tylenol Extra Strength Rapid Release Gelcaps over the many other acetaminophen products which Defendant produces and advertises because "she hoped for faster relief of pain." Complaint at ¶ 67; *see also id.* at ¶ 21, 26, 29 (discussing Defendant's other

[1] The Court takes judicial notice of the three documents appended to Defendant's motion as most of them were official publications issued by government agencies and, separately, the facts contained with them are not subject to reasonable dispute. *See In re Zyprexa Prods. Liab. Litig.*, 549 F. Supp. 2d 496, 501 (E.D.N.Y. 2008) ("Public documents issued by government agencies such as the Food and Drug Administration ("FDA") may also be considered.")

acetaminophen products). Plaintiff now alleges that, despite Defendant's labeling and advertising of the Rapid Release Gelcaps, the product does not work faster than their cheaper tablet alternatives. *Id.* at ¶ 69. In support of her assertion, Plaintiff relies on a 2018 study analyzing the comparative dissolution rates of Rapid Release Tylenol against one of its non-rapid release Johnson & Johnson counterparts and other acetaminophen products on the market. *Id.* at ¶ 57. The 2018 study found that the Rapid Release gelcaps and tablets reached 80% dissolution in 3.94 minutes whereas Defendant's Tylenol tablets reached the same dissolution in only 3.56 minutes. *See* Mot., Ex. A, at 1, 2, 4.

III. Relevant Regulations

The Food, Drug, & Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA"), grants the Food & Drug Administration ("FDA") the power to regulate the labeling and marketing of over-the-counter ("OTC") drugs. *See also* 21 C.F.R. § 201.66. The FDCA also contains an express preemption clause which bars "state[s]" and "political subdivision[s]" thereto from:

> Establish[ing] or continu[ing] in effect any requirement – (1) that relates to the regulation of a drug that is not subject to the requirements of section 353(b)(1) or 252(f)(1)(A) of this title [including OTC drugs]; and (2) is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter.

21 U.S.C. § 379r(a). From 1972 to 2020, The FDA employed a four-step process when issuing binding regulations on OTC drugs. *Bischoff v. Albertsons Co.*, 678 F. Supp. 3d 518, 523 n.2 (S.D.N.Y. 2023) (citing *In re Acetaminophen - ASD-ADHD Prods. Liab. Litig.*, No. 22-CV-8830, 2023 U.S. Dist. LEXIS 69605 (S.D.N.Y. Apr. 20, 2023)). That process includes the following steps:

> (1) an advisory review panel [is] established to evaluate the safety and effectiveness of the OTC drug; (2) the advisory review panel submit[s] its report to the FDA Commissioner; (3) the FDA publishe[s] a tentative final monograph ("TFM"); and (4) after receiving comments on the TFM, the FDA publishe[s] a final monograph.

Id. The FDA published a tentative final monograph on acetaminophen in 1988 which set the "conditions under which a category of OTC drugs or specific OTC drugs [including acetaminophen] are generally recognized as safe and effective and not misbranded." 21 C.F.R. § 330.10(a)(7)(i). The 1988 monograph sets forth dissolution standards for acetaminophen tablets. In order to be lawfully referred to as "immediate release," the acetaminophen tablet must dissolve by at least 80% after 30 minutes. *See Sapienza v. Albertson's Co., Inc.*, No. 22-10968-RGS, 2022 U.S. Dist. LEXIS 217368, at *2 (D. Mass. Dec. 2, 2022). The 1988 tentative monograph then became a final order upon the passage of the CARES Act in 2020. *See Bischoff*, 678 F. Supp. at 524.

The FDA has also published two non-binding guidance documents on acetaminophen dissolution rates. One guidance states that "immediate release solid oral drug products" have a "dissolution criterion [of] Q=80% in 30 minutes" and the other states that an immediate release drug is "considered rapidly dissolving when a mean of 85 percent or more of the labeled amount of the drug substance dissolves within 30 minutes," and "considered very rapidly dissolving when a mean of 85 percent or more of the labeled amount of the drug substance dissolves within 15 minutes." ECF No. 40-3 at 3

LEGAL STANDARD

When considering a 12(b)(6) motion, a court should "draw all reasonable inferences in [the plaintiff's] favor, assume all well-pleaded factual allegations to be true, and determine whether they plausibly give rise to an entitlement of relief." *Faber v. Metro Life Ins. Co.*, 648

F.3d 98, 104 (2d Cir. 2011) (internal quotation marks omitted). Thus, "[t]o survive a motion to dismiss, a complaint must contain sufficiently factual matter accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp v. Twombly*, 550 U.S. 544, 570 (2007)). The Court's function on a motion to dismiss is "not to weigh the evidence that might be presented at a trial but merely to determine whether the complaint itself is legally sufficient." *Goldman v. Belden*, 754 F.2 1059, 1067 (2d Cir. 1985). A reviewing court ought not dismiss a complaint where "enough facts to state a claim to relief that is plausible on its face" have been plead." *Twombly*, 550 U.S. at 570. "A claim has facial plausibility when plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. Moreover, "the tenet that a court must accept a complaint's allegations as true is inapplicable to threadbare recitals of a cause of action's elements, supported by mere conclusory statements." *Id.* at 663.

State laws that conflict with federal law are without effect under the Supremacy Clause. *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516, 112 S. Ct. 2608, 120 L. Ed. 2d 407 (1992). While there is a general presumption against preemption, *Truss v. Bayer Healthcare Pharms. Inc.*, No. 21-CV-9845, 2022 U.S. Dist. LEXIS 207421 at *6 (S.D.N.Y. Nov. 15, 2022), that presumption is overcome "where . . . Congress has expressly manifested its intent to preempt state law." *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 319 (S.D.N.Y. 2017). When considering whether a federal statute expressly preempts state laws, "courts focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent." *Id.* A federal statute which overrides a state's "requirements," preempts not only statutory law and regulations but also covers "common-law duties." *Cipollone*, 505 U.S. at 443

(quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005)). "A common law rule that 'requires that manufacturers label or package their products in [a] particular way' qualifies as a requirement with respect to labeling." *Bischoff*, 678 F. Supp. at 523 (citing *Bates*, 544 U.S. at 443). Said succinctly, "[a] state law that applies to drugs . . . is preempted if it imposes a requirement that is not identical to the requirements of the FDCA and the FDA's regulations." *Bimont v. Unilever U.S., Inc.*, No. 14-CV-7749, 2015 U.S. Dist. LEXIS 119908, at *6 (S.D.N.Y. Sept. 9, 2015).

DISCUSSION

Defendant argues that the 1988 monograph's requirements for "immediate release" labeling on OTC drugs like acetaminophen preempts Plaintiff's New York state common law claims. In support of their argument, Defendants encourage this Court to follow the decisions made in *Bischoff v. Albertsons Co.*, 678 F. Supp. 3d 518 (S.D.N.Y. 2023), *Sapienza v. Albertson's Co., Inc.*, No. 22-10968-RGS, 2022 U.S. Dist. LEXIS 217368 (D. Mass. Dec. 2, 2022), and *Morgan v. Albertsons Co.*, No. 22-cv-02948-JST, 2023 U.S. Dist. LEXIS 93108 (N.D. Cal. Mar. 13, 2023).

The *Bischoff*, *Sapienza*, and *Morgan* courts all came to the same conclusion that similar allegations as to "rapid release" acetaminophen products were preempted by the FDCA's regulation of "immediate release" tablets. These Courts came to the same conclusion through similar analytical means. The *Bischoff* and *Sapienza* Courts found that the "immediate release" and "rapid release" terms both referred to the products dissolution rate and were sufficiently similar such that they were covered by the FDA regulations. 2022 U.S. Dist. LEXIS 217368, at *8; *see also* 678 F. Supp. at 527 ("[I]t would be nonsensical to allow a manufacturer to evade an FDA requirement simply by coming up with a phrase that addresses the subject matter of the

regulation but in different phraseology.") The *Morgan* Court, on the other hand, went so far as to find that "[a]s a matter of logic," the FDA regulation's "designation of the gelcaps as 'immediate release' *encompasses* a representation of those gelcaps as 'rapid release.'" 2023 U.S. Dist. LEXIS 93108, at *16.

Plaintiff, as was the case before the *Bischoff*, *Sapienza*, and *Morgan* Courts, draws a strong distinction between the Tentative Final Monograph's usage of the term "immediate release" and the Defendant's "Rapid Release" product. Plaintiff alleges that the FDA's dissolution regulation does not apply where the exact same nomenclature is not employed. Plaintiff attempts to distinguish *Bischoff*, *Sapienza*, and *Morgan* by alleging that these cases improperly "minimize[d] the consequential—and highly deceptive—effect of conflating such terms when used in labeling and advertising." Opp. at 5. Plaintiff then asks this Court to follow the Northern District of California's decision in *Bailey v. Rite Aid Corporation* which interpreted the FDA's aforementioned guidance documents as "suggest[ing] that 'immediate' and 'rapid' are not synonymous." No. 18-cv-06926-YGR, 2019 U.S. Dist. LEXIS 153498, at *13 (N.D. Cal. Sep. 9, 2019). Holding so, in Plaintiff's eyes, would cause this Court to find that the Tentative Final Monograph and guidance documents' differing standards for "immediate release" and "rapidly dissolving" products renders the FDA's regulations inapplicable to Defendant's "rapid release" product.

This Court disagrees with Plaintiff's argument and joins the majority of its sister district courts in their holdings here. As this Court has previously held,

> Where federal requirements address the subject matter that is being challenged through state law claims, such state law claims are preempted to the extent they do not impose identical requirements. Thus, although the standard of identity does not define the term "pure" or specify when it is permissible to place a cartoon-like image of a mountain range on a purified water label, the FDA considered misrepresentations regarding source and chose to regulate the labeling requirements for the disclosure of source information, and in so doing it determined that purified water should be exempted. Accordingly, any state law claims premised on a misrepresentation about the source of purified water are preempted.

In re Pepsico, Inc., 588 F. Supp. 2d 527, 538 (S.D.N.Y. 2008). And as *Bischoff* counsels,

> That the FDA did not use the exact words "rapid release" in its regulations surely cannot mean that the FDA does not regulate the subject matter of OTC acetaminophen dissolution standards where, as described in detail above, it has published regulations and guidance addressing when an OTC acetaminophen product can be considered "immediate release," "rapidly dissolving," and "very rapidly dissolving."

678 F. Supp. 3d at 526-527. Just as a different district court in the Northern District of California declined to apply *Bailey* because it improperly "relied on . . . non-binding FDA guidance," 2023 U.S. Dist. LEXIS 93108, at *18, and just as *Bischoff* declined to do this because *Bailey*'s holding could not be squared with *In re Pepsico, Inc.*'s rejection of "the principle that state requirements are permitted as long as the federal standard does not specifically address the terms or images at issue," this Court does the same. 588 F. Supp. 2d at 538.[2]

[2] Plaintiff's reliance on *McFall v. Perrigo Company* and *Canale v. Colgate-Palmolive Company* is also unconvincing. The Court in *McFall*, considering similar claims as to acetaminophen products labeled for use by "children" and "infants," denied defendant's preemption argument largely on the grounds that the FDA's regulations clearly delineated between the two classes of end users. No. 2:20-cv-07752-FLA (MRWx), 2021 U.S. Dist. LEXIS 109451, at *27-28 (C.D. Cal. Apr. 15, 2021) (interpreting the FDA's 1988 Tentative Final Monograph in accordance with a previously-issued regulation directing OTC drug manufacturers to "qualify any reference to 'infant'" in a particular way). No such duly-enacted regulation delineating between "immediate release" and "rapid release" acetaminophen products exists here.
Canale, which considered similar consumer claims relating to whitening toothpaste, ultimately denied defendant's preemption claims because the FDA had not issued any regulations as to teeth whitening. 258 F. Supp. 3d 312, 320-321 (S.D.N.Y. June 23, 2017). The *Canale* defendant was only able to present a regulation on anticaries toothpaste which was distinct from whitening. *Id.* The 1988 Tentative Final Monograph, on the other hand, clearly applies to the product and feature at issue in this case (i.e. acetaminophen dissolution rates).

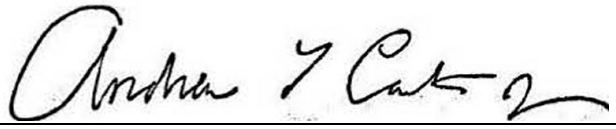
Perhaps in hopes of side-stepping this precedent and the issue of preemption altogether, Plaintiff advances an additional theory of this case. This theory proceeds by characterizing the FDA's regulations as singularly governing acetaminophen drug labeling and having no effect on the advertisement, marketing, or pricing of acetaminophen products. In support of their view of the law, Plaintiff cites to *Edwards v. Walmart, Inc.* in which defendant's preemption defense was denied on substantially the same facts as here. No. CV 18-9655-GW(FFMx), 2019 U.S. Dist. LEXIS 230993 (C.D. Cal. Apr. 18, 2019). As an initial matter, the Court notes *Edwards*' inapplicability to this case. *Edwards* denied preemption because of defendant's failure to "provide[] any binding regulation (or other applicable federal law)." 2019 U.S. Dist. LEXIS 230993 at *15. In so doing, the *Edwards* defendant failed to make out their affirmative defense. Clearly no such pleading deficiency exists in this case. Zooming out, the Court also finds Plaintiff's larger theory wholly unworkable. To hold that the FDA's regulation of acetaminophen dissolution rates ought not control simply because a drug producer markets or prices several of its qualifying "immediate release" products in varying manners would be to create an end-run around the FDCA's express preemption clause. Much ink has been spilled on the separation of powers interests which undergird the Court's decision on this front. *Sapienza* notes that "Congress's adoption of a preemptive scheme . . . ensures that the legal rules governing complex areas of the economy or products are formulated by expert regulators with a broad national perspective and needed scientific or technical expertise, rather than by decision makers—such as municipal officials, elected state judges, and lay juries—who may have a far more parochial perspective and limited set of information." 2022 U.S. Dist. LEXIS 217368, at *9 (citing Alan Untereiner, *The Defense of Preemption: A View from the Trenches*, 84 Tul. L. Rev. 1257, 1262 (2010)).

CONCLUSION

Therefore, the Court grants Defendant's motion to dismiss on preemption grounds. Dismissal is granted with prejudice. "The problem[s] with [Plaintiff's] causes of action [are] substantive . . . [and] better pleading will not cure [them]." *Cuoco v. Moritsugu*, 222 F.3d 99, 112 (2d Cir. 2000).

SO ORDERED.

Dated: **August 27, 2024**
New York, New York



ANDREW L. CARTER, JR.
United States District Judge